

## TCT-689

**Percutaneous Closure Of The Left Atrial Appendage: Initial Experience In Latin America**

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**Background:** Atrial fibrillation (AF) is the most common cardiac arrhythmia and a major cause of morbidity and mortality secondary to cardioembolic stroke. Percutaneous closure of the left atrial appendage (LAA) has emerged as an alternative to anticoagulation therapy for the prevention of cerebrovascular events in patients with AF and a contraindication or difficulties for oral anticoagulation. This study describes the feasibility, in hospital and follow up results of the transcatheter closure of the LAA with the Amplatzer Cardiac Plug (ACP; StJude, Minneapolis; MN) in an initial Latin American experience.

**Methods:** Physician initiated voluntary registry, including 60 consecutive patients with AF at high risk for cardioembolic stroke, from different Latin American hospitals that were treated with the ACP, from August 2009 to June 2012. The procedures were performed under general anesthesia, transesophageal echocardiography (TEE) and fluoroscopic guidance. Clinical and TEE follow up was performed at 30 days, and clinical follow up thereafter.

**Results:** 60 patients were included. Age  $72 \pm 8.7$  years; male 70%; hypertensive 78%; congestive heart failure 32.17%; CHADS2 score  $3.15 \pm 1.1$ ; contraindications to oral anticoagulation 64.3% LAA neck diameter was  $20.3 \pm 3.8$  mm by TEE and  $22.6 \pm 3.2$  by angiography. LAA occlusion was attempted and successfully achieved in all 60 patients, and in 3 cases, simultaneous closure of the LAA and PFO was performed. The implanted device size was  $25 \pm 2.9$  mm. There were serious in hospital complications in 5 patients (8.3%). 1 patient experienced device embolization that required surgical retrieval, and 4 (6.6%) patients presented severe pericardial effusion (SPE) requiring pericardiocentesis. For patients with (SPE) hospitalization was longer  $4.25 \pm 1.25$ , vs  $2.77 \pm 2.10$  days for patients without SPE  $p=0.174$ . There were not in hospital deaths, stroke, or myocardial ischemia. No new events were reported at 30 days clinical follow up. 88% of patients underwent TEE at 30-45 days without evidence of flow to the LAA or thrombus on device. Median follow up was 12.5 months, without strokes.

**Conclusions:** In this initial experience, percutaneous closure of the LAA with the ACP in patients with AF at high risk of stroke, was feasible, with a high technical success and in hospital complications rate similar to previous reports with these and other devices during the learning phase of the procedure. The results at follow up are encouraging.

## TCT-690

**A new method to select device size for atrial septal defect closure based on the largest defect diameter and area on real time three-dimensional transesophageal echocardiography.**

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**Background:** Device selection for percutaneous atrial septal defect (ASD) closure is usually based on balloon sizing (BS) of the defect. This step is crucial to avoid under or oversizing and resultant complications. Although three-dimensional (3D) transesophageal echocardiography (TEE) has been used to guide the procedure, its role in determining accurate device selection remains an open area for research. We studied the use of 3D TEE as a possible surrogate for BS for proper device selection in ASD closure.

**Methods:** Patients underwent percutaneous ASD closure under general anesthesia and 3D TEE monitoring. Largest and smallest diameters of the ASD, the areas of the defect, sizing balloon and selected device waist were recorded as well as the characteristics of the interatrial septum (IAS). BS with the PTS balloon was performed using the "stop-flow" technique. A Cera device (Lifetech, China) the same size of the BS diameter or 1 mm larger was selected for implantation. Linear regression analyses were employed to determine what was the best baseline parameter on 3D TEE to predict adequate device selection. T tests or Mann-Whitney tests were used as applicable.

**Results:** Twenty-five adult patients (mean age:  $42 \pm 15$  years) were enrolled. Six had redundant or aneurysmal IAS. In the entire cohort ASDs were oval measuring  $19.6 \pm 6.5 \times 14.2 \pm 4.5$  mm ( $p < 0.001$ ). The BS and selected device waist diameters were  $22.3 \pm 6.0$  and  $21.9 \pm 5.8$  mm, respectively ( $p = \text{NS}$ ). The area of the ASD, sizing balloon and device waist were  $262.8 \pm 144.7$ ,  $416.4 \pm 226.6$ ,  $402.2 \pm 196.9$  mm<sup>2</sup>, respectively ( $p = \text{NS}$  between balloon and device areas). After device release waist

diameter and area were  $19.6 \pm 5.2$  mm ( $p = \text{NS}$ ) and a median of 281 mm<sup>2</sup> (73-677) ( $p = 0.081$ ), respectively, similar to pre-implantation values. In patients with thicker, non-redundant IAS there was an excellent correlation between the largest ASD diameter ( $R = 0.954$ ;  $R^2 = 0.911$ ) and the ASD area ( $R = 0.929$ ;  $R^2 = 0.864$ ) on 3D TEE and the selected device diameter. A poor correlation was observed for patients with redundant/aneurysmal IAS. The regression equations that were obtained for proper device size selection were Device size (mm) = (Largest 3D TEE ASD diameter  $\times 0.888$ ) + 3.911 mm and Device size (mm) = 11,859 + (0.0374  $\times$  3D TEE ASD area).

**Conclusions:** The largest ASD diameter and the ASD area on 3D TEE were excellent surrogates for BS in patients with thicker, non-redundant IAS. The application of this new method for device selection may help to expedite the procedure and avoid oversizing. These observations should be validated in prospective trials.

## TCT-691

**Gallium SPECT/CT and PET/CT Fusion Imaging for the Assessment of Prosthetic Valve Endocarditis Prior to Percutaneous Paravalvular Leak Closure**

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**Background:** Endocarditis is a risk factor for and sequelae of surgical prosthetic paravalvular leaks (PVLs). The modified Duke Criteria is the gold standard for diagnosing infective endocarditis. Nonetheless, it has never been evaluated for prosthetic valve endocarditis (PVE). Concern remains regarding the safety of percutaneous PVL closure in patients at high risk for PVE.

**Methods:** We evaluated patients from January 2012 to June 2013 who presented for symptomatic PVL closure. High-risk for PVE was defined as a modified Duke Criteria that met at least 1 major and 1 minor criteria aside from a predisposing heart condition. Gallium SPECT (24  $\pm$  48 hours) or PET imaging were fused with cardiac CT. Patients with positive studies either underwent surgical valve replacement (SVR) or 6 weeks of intravenous antibiotics followed by repeat nuclear study, with subsequent intervention if resolved. Patient with negative studies underwent percutaneous closure.

**Results:** 62 patients were evaluated with 11 patients deemed high risk for PVE (65  $\pm$  13 years, 100% heart failure, 37% hemolysis). Definite criteria were met in 27% (2 major  $n=2$ ; 1 major 3 minor  $n=1$ ). Two patients had positive nuclear studies and underwent SVR and 1 patient had a negative study and underwent SVR after unsuccessful closure, with negative surgical cultures. Possible criteria were met in 72% (1 major 1 minor or 2 minor with echocardiogram concerning for abscess  $n=2$ ; 1 major 2 minor  $n=6$ ). 2 patients with abnormal echocardiograms had positive nuclear studies and died (1 intraoperative with positive cultures, 1 inoperable). Two patients had positive studies and successful closure after antibiotics and negative repeat imaging. The remaining 4 patients had negative nuclear studies and successful closure. On follow-up (8.5  $\pm$  8 months), no PVE was identified with improvement in NYHA by  $\geq 1$  and complete hemolysis resolution.

**Conclusions:** Early experience of Gallium SPECT/CT or PET/CT identifies a potential role in the assessment of PVE in PVL patients. Further evaluation on the utility of nuclear fusion imaging in this patient population is necessary.

## TCT-692

**Left atrial appendage closure: Single-center experience with the 4th generation Watchman device**

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**Background:** The WATCHMAN left atrial appendage (LAA) Closure Device has been shown to be at least equivalent to anticoagulation for stroke prevention in patients with non-valvular atrial fibrillation (NVAf). A newer, (fourth) generation WATCHMAN device (with a less traumatic distal tip and option of recapture and redeployment) was designed to facilitate delivery and improve the safety profile, particularly the incidence of pericardial effusions. The aim of this study was to evaluate the feasibility and safety of the newer (fourth) generation WATCHMAN left atrial appendage (LAA) closure device.

**Methods:** This was a prospective, single-center, non-randomized study of LAA closure in 36 patients with NVAf.

**Results:** Between February 2010 and June 2011, 36 patients (mean age:  $72 \pm 16$  years, male: 66.7%, median CHADS2 of 2.83, median CHA2DS2-VASc of 4.5) with NVAf underwent percutaneous LAA closure with the newer (fourth)